

REMARKS

Claims 1-21 are pending in the application and of those claims, claims 2, 11-13, and 16 are withdrawn from consideration. Claims 1, 3-10, 14, 15, 17-21 stand rejected. Claims 1, 6, and 15 have been amended herein. Claims 5 and 19 have been cancelled herein.

Claim Amendments

Support for amendments to claims 1, 6, and 15 may be found at least in the claims originally filed, the figures, and in paragraph [0104] describing a radially deflectable needle retainer.

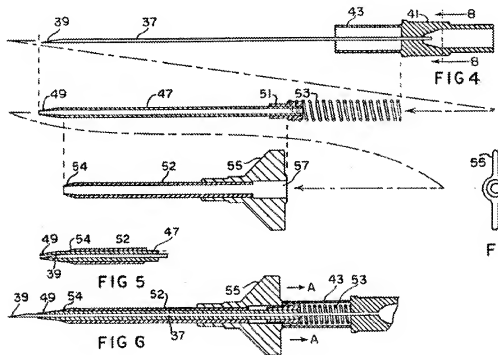
Claim Rejections – 35 U.S.C. § 102

Claims 1, 3, 5-10, 14, 15, 17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Laughlin (U.S. Patent No. 5,295,974).

O'Laughlin discloses a shielded hypodermic needle with a winged base that is pulled back to expose the needle point.

With reference to FIGS. 4-6 of O'Laughlin, the needle 37 includes a base adapter 41 and a guideway 43 (the alleged elongated arm). The needle 37 is configured to fit inside of a barrel 47 which includes a spring 53 attached to the base 51 of the barrel 47. The barrel 47 with the needle 37 are inserted within a cannula sleeve 52. As shown by FIG. 6, when the needle 37 is to be used for insertion of the cannula 52 in a patient, the winged base 55 of the cannula 52 is pulled back against the guideway 43, thereby

compressing the spring 53. This pulls the barrel 47 back against the force of the spring 53 and exposes the tip 39 of the needle 37. When the winged base 55 is released before the needle 37 and the barrel 47 are withdrawn from the patient, the spring 53 extends and pushes the end 49 of the barrel 47 over the tip 39 of the needle 37.



FIGS. 4-6 of O'Laughlin

Amended claims 1 and 15 of the Present Application, recite a *radially deflectable* needle retainer fixedly connected with the needle and releasably retaining the needle in the extended position, comprising an elongated arm. Amended claim 6 recites a *radially deflectable* needle retainer operable between a latched position and an unlatched position. By way of example, and not limitation, in the present application, while referring to FIGS. 21-27, states:

The needle retainer 740 comprises an elongated resiliently flexible arm fixedly connected with the needle 730. The forward end of the needle retainer projects through an opening at the forward end of the housing adjacent the tip 722. The forward portion 746 of the needle retainer engages the side of the catheter hub 772. Similar to the previous embodiment, the catheter hub 772 wedges the needle retainer arm radially outwardly so that a ridge 745 on the arm engages a lip 724 formed by the opening at the forward end of the housing. Accordingly, when the catheter 770 is removed from the device 710, the needle retainer 740 deflects inwardly to release the needle 730. The spring then propels the needle rearwardly into the housing 720.

(Present Application, page 25, line 23 through page 26, line 5).

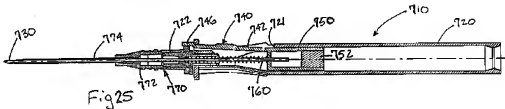


FIG. 25 of the Present Application

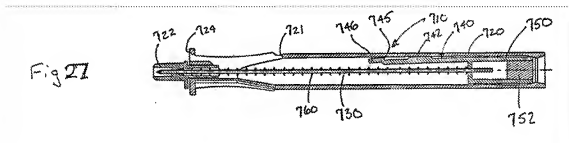


FIG. 27 of the Present Application

As shown by FIGS. 4-6 of O'Laughlin, the base adapter 41 (alleged needle retainer) and the guideway 43 (the alleged elongated arm) do not include a radially deflectable needle retainer fixedly connected with the needle and releasably retaining the needle in the extended position with an elongated arm.

Additionally, the needle 37 is only exposed by a user manually pulling back on the winged base 55. As such, the needle 37 of O'Laughlin is not releasably retained in the extended position by an elongated arm—the needle 37 is only extended by manually retracting the winged base 55.

Moreover, neither the base adapter 41 or the guideway 43 are a radially deflectable needle retainer. The guideway 43 is a circular sleeve configured to house the spring 53 and may serve to limit the backward movement of the winged base 55. The Office Action, page 2, alleges that the guideway 43 acts as a latch and may be compressed. However, Applicants respectfully submit, that even if the guideway 43 could be compressed, the compression would not “latch” the winged base 55 or retain or delay the release of the cannula sleeve 52 or the winged base 55. There is nothing on the winged base 55 for the guideway 43 to latch onto. As shown by FIG. 6 of O'Laughlin, the guideway 43 is just a guideway for the spring 53 and may act as a bump-stop for the winged base 55, but is not a latch. As such, the guideway 43 is not capable of impeding retraction of the needle as recited by independent claim 14. Also, even if the guideway 43 could be compressed, it is not radially deflectable as required by claims 1, 6, and 15.

In addition, O'Laughlin does not disclose a needle retainer that releases the needle upon disengagement of the catheter from the arm allowing the biasing element to propel the needle rearward. Referring to O'Laughlin Col. 6, lines 20-40, a user must manually retract and maintain the barrel 47 in the retracted position, by pulling back against the winged base 55. Upon withdrawing the needle 37, the pull-back pressure must be released by the user in order for the barrel 47 to re-extend over the tip 39 of the

needle 37. The needle 37 is not propelled rearward, the barrel 47 is extended forward against the base adapter 41. Furthermore, the re-extension of the barrel 47 does not depend on the disengagement of the catheter.

Independent amended claim 6 of the Present Application, recites a needle retainer operable between a latched position and an unlatched position, wherein in the latched position the needle retainer retains the needle in the extended position against the bias of the biasing element, and wherein the needle retainer is configured to automatically release the needle upon disengagement of the catheter from the housing. As discussed above, the the guideway 43 is just a guideway for the spring 53 and may act as a bump-stop for the winged base 55, but is not a latch. Therefore, O'Laughlin does not disclose a radially deflectable needle retainer that operates between a latched or unlatched position and is configured to automatically release the needle upon disengagement of the catheter from the housing.

Independent claim 14 of the Present Application recites a method for inserting an IV catheter including a needle retainer for releasably retaining the needle so that the needle projects forwardly from the housing and disengaging the engagement of the catheter with the housing, wherein the disengagement of the catheter causes the needle to begin retracting into the housing. Likewise, independent claim 15 of the Present Application recites a needle retainer comprising an elongated arm and fixedly connected with the needle and releasably retaining the needle in the extended position.

As discussed previously, the hypodermic needle of O'Laughlin operates between a shielded position and an un-shielded position but is not retained in a forwardly projecting position by any needle retainer. The user must manually retract and maintain

the barrel 47 in the retracted position by pulling back against the winged base 55, thereby exposing the tip of the needle. Furthermore, upon withdrawing the needle 37, the user must release the barrel 47 to re-extend over the tip 39 of the needle 37.

Accordingly, O'Laughlin does not disclose each and every element of independent claims 1, 6, 14 and 15. For at least these reasons, claims 1, 6, 14 and 15 and their respective dependent claims are patentable over O'Laughlin.

Claims 1, 3, 4-10, 14, 15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang *et al.* (U.S. Patent No. 5,419,766).

Chan *et al.* disclose a catheter stick protector having a tip protector with a metal flap clip and also including a sleeve of material attached at one end to a needle hub and at a second end to the tip protector. Referring to FIG. 1 of Chan *et al.*, the tip protector 11 is attached to the distal end 12 of a corrugated sleeve 9. With reference to FIG. 2C, the tip protector 11 is designed to be slidable received on the needle 4 such that it may slide from a proximal location to a position that is extended therefrom in which the tip protector 11 covers the distal end 14 of the needle 4. When the tip protector 11 is extended over the needle 4, the corrugated sleeve 9 is drawn distally until it extends around the barrel of the needle 4.

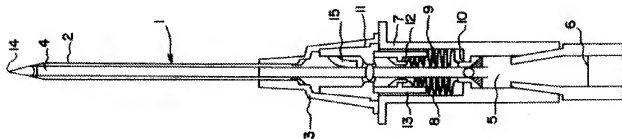


FIG. 1 of Chan *et al.*



FIG. 2C of Chan *et al.*

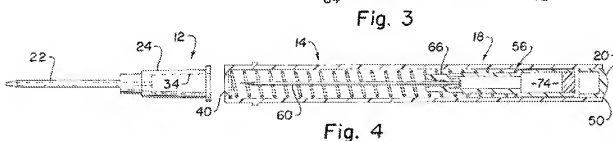
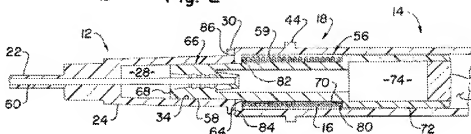
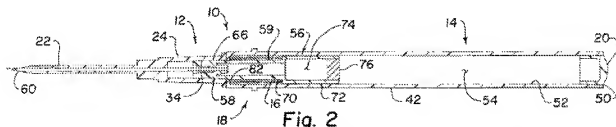
Independent claims 1, 6, and 15 recite a biasing element biasing the needle toward the retracted position. Chan *et al.* do not disclose a biasing element. The corrugated sleeve 9 of Chan *et al.* is not a biasing element, but is a sleeve designed to cover the needle upon extending the tip protector 11.

Independent claim 14 recites a method of inserting an IV catheter, comprising disengaging the engagement of the catheter with the housing, wherein the disengagement of the catheter causes the needle to begin retracting into the housing. Chan *et al.* do not disclose a device wherein the disengagement of the catheter causes the needle to begin retracting into the housing. Furthermore, Chan *et al.* do not disclose a needle capable of retracting.

Accordingly, Chan *et al.* do not disclose each and every element of independent claims 1, 6, 14 and 15. For at least these reasons, claims 1, 6, 14 and 15 and their respective dependent claims are patentable over Chan *et al.*

Claims 1, 3, 4, 5, 15 and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw *et al.* (U.S. Patent No. 5,989,220).

Referring to FIGS. 2-4 of *Shaw et al.*, the retraction body assembly 18 includes a retraction body 56 that has a front portion 58 (alleged elongated arm) carrying a catheter insertion needle 60, and an enlarged rear portion 72 (alleged needle retainer). The front portion 58 of retraction body 56 extends into the hollow connector 24 of the catheter connector assembly 12, with the surface 66 in frictional engaging contact with surface 34. As such, a friction fit between the surface 66 and surface 34 holds the retraction body assembly 18 in place against the force of the biasing element 16.



FIGS. 2-4 of *Shaw et al.*

Amended independent claims 1 and 15 recite a *radially deflectable* needle retainer fixedly connected with the needle and releasably retaining the needle in the extended position, comprising an elongated arm. *Shaw et al.* do not disclose or suggest

a radially deflectable needle retainer comprising and elongated arm. As shown in FIGS. 2-4 of Shaw *et al.*, the enlarged rear portion 72 or the front portion 58 are not radially deflectable.

Accordingly, Shaw *et al.* do not disclose each and every element of independent claims 1 and 15. For at least these reasons, claims 1 and 15 and their respective dependent claims are patentable over Shaw *et al.*

CONCLUSION

In view of the foregoing, Applicants submit that the claims define patentable subject matter and a Notice of Allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the telephone number given herein.

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Respectfully submitted,

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